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McDermott, Will & Emery

June 6, 2002

VIA FEDERAL EXPRESS

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane (Room 1061) Rockville, Maryland 20852

Re:

Bayer AG

FDA Docket: 00N-1571

Dear Sir/Madam:

Enclosed for filing please find an original and two copies of Respondent Bayer Corporation's Motion to Clarify June 4, 2002 Order Regarding Correction of the Record. Please return a file-stamped copy in the enclosed self-addressed stamped envelope.

Please call with any questions.

Sincerely.

Robert B. Nicholas

RBN:jeh Enclosures

WDC99 609970-1.048250.0013

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:

Enrofloxacin for Poultry: Withdrawal of Approval of New Animal Drug Application NADA 140-828 FDA DOCKET: 00N-1571

BAYER'S MOTION TO CLARIFY JUNE 4, 2002 ORDER REGARDING CORRECTION OF THE RECORD

On May 20, 2002, CVM filed a Motion for Leave to Correct the Record. This motion sought to redact and/or withdraw various documents that contained confidential information that CVM had placed in the public docket in error. On June 4, 2002, Administrative Law Judge Davidson issued an Order in response to this motion addressing certain documents that will be treated as confidential by the Parties in the above-captioned hearing. Bayer has reviewed the Order and respectfully requests that the Administrative Law Judge clarify a portion of the Order that places documents in the confidential docket.

With respect to documents to be placed in the confidential docket, the Order states that:

And it is FURTHER ORDERED that the unredacted version of these documents will be subject to a protective order under the following terms:

- 1. Unreducted versions of G-341, G-682, G-837, G-872, G-916 and G-937 shall be placed in the confidential docket.
- 2. Parties and participants shall treat unreducted documents G-682, G-837, G-872, and G-937 as confidential and shall not further disclose them to any other person.

Order at 2.

WDC99 609148-2.048250.0013 O(N-/5¹⁷/

RHU7

Bayer seeks to clarify that parties and participants (including attorneys and client personnel) and their witnesses will have access to all documents placed in the confidential docket

subject to the restrictions placed in Judge Davidson's Order, and to be used solely for the purpose

of the hearing in this matter.

Bayer has consulted with CVM and AHI about this motion. CVM does not oppose this

motion. AHI concurs in the motion.

Respectfully submitted,

Robert B. Nicholas

James H. Sneed

Gregory A. Krauss

M. Miller Baker

McDERMOTT, WILL & EMERY

600 Thirteenth Street, N.W.

Washington, D.C. 20005

(202) 756-8000

Attorneys for Bayer

CERTIFICATE OF SERVICE

I hereby certify that a copy of Bayer's Motion to Clarify June 4, 2002 Order Regarding Correction of the Record, was mailed this 6th day of June, 2002, via first-class mail, postage pre-paid to:

Kent D. McClure Animal Health Institute 1325 G Street, N.W., Suite 700 Washington, D.C. 20005

I hereby certify that a copy Bayer's Motion to Clarify June 4, 2002 Order Regarding Correction of the Record, was e-mailed and also mailed, postage pre-paid, this 6th day of June, 2002 to:

Nadine R. Steinberg, Esquire Food and Drug Administration Office of General Counsel (CGF-1) 5600 Fischers Lane, Room 7-77 Rockville, MD 20857

Robert B. Nicholas

UNITED STATES OF AMERICA BEFORE THE FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:

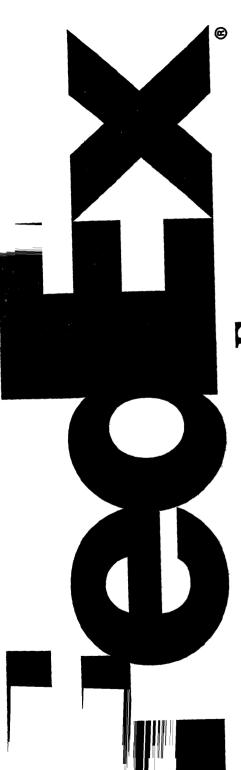
Enrofloxacin for Poultry: Withdrawal of Approval of New Animal Drug Application NADA 140-828 FDA DOCKET: 00N-1571

ORDER

UPON CONSIDERATION of Bayer's Motion to Clarify June 4, 2002 Order Regarding Correction of the Record, it is hereby

ORDERED that all parties and participants (including attorneys and clients personnel) and witnesses will have access to all documents contained in the confidential docket. However, these individuals shall not further disclose them to any other person, and the use of documents in the confidential docket shall be limited to those related to the hearing in this matter.

DATED this the day of June, 2002.	
Α.	
	Daniel J. Davidson
	Administrative Law Judge



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